K003890

MAY 22 2001

APPENDIX I

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I.* Submitter; George Wiseman, Ultralink, LLC, 2083 Hawaii Ave., N.E., St. Petersburg, Florida, Phone: 727-527-1277.
II. Classification Names and numbers: Ultrasonic pulsed echo imaging system, 90-IYO, FR number 892.1560.
III. Common/Usual Name: Ultrasound Bio Microscope
IV. Proprietary Names: Artemis™ (VHF Ultrasonic Arc-Scan System)

V. Establishment Registration Number: in progress.

VI. Classification: Class II, Tier II. Described in CFR 892.1560

VII. Substantial Equivalence: The Artemis® is substantially equivalent to the classified device described in CFR 21 892.1560, "Ultrasonic Pulsed Echo Imaging System," and to other ultrasound systems that have been cleared by the 510(k) process, particularly the "Digital Ophthalmic ultrasound Biomicroscope," cleared by Zeiss Humphrey System in K-923211. It is also substantially equivalent to the "Pocket Ultrasonic Ophthalmic Pachymeter, Biometry," cleared by Quantel Medical in K-993674, to the "DGH-500 Pachymeter, cleared in K920906 by DGH Technology, Inc., and to the "Humphrey OCT (Optical Coherence Tomography) Scanner," cleared by Humphrey, Inc., in K944523

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to produce high-resolution ultrasound images of the anterior portion of the eye, and to measure these tissues such as the thickness of the cornea and its individual layers, the epithelium, stroma and surgically induced surfaces. They can also be used to measure pathologic structures such as solid masses and cysts.
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market except for differences in position of the patients head and presentation of the derived data.

3. Descriptive information provided shows that the materials from which Mucopren™ is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.

4. The guidance document, "Information for Manufacturers.....of Ultrasound Systems and transducers. The acoustic output of this device is similar to that of predicate devices and well below the preamendment levels described in the guidance.

5. The FDA "Decision-Making Process" chart was also used in reaching our claims that the product was substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2001

Mr. George D. Wiseman
President and CEO
Ultralink, LLC
2083 Hawaii Ave., N.E.
ST. PETERSBURG FL 34134

Re: K003890
Trade Name: Artemis[R] (VHF Ultrasound Arc-Scan System)
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: March 26, 2001
Received: March 28, 2001

Dear Mr. Wiseman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Artemis[R] (VHF Ultrasound Arc-Scan System), as described in your premarket notification:

Transducer Model Number

50 MHz Panametrics Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

APPENDIX II

Diagnostic Ultrasound Indications for Use Form

Page: 1 of 1
510(k) Number (if known): [redacted] K003890
Device Name: Artemus ultrasonic pulsed echo imaging system
Intended Use: To measure areas and thickness of components of the eye.

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	X	X								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional comments: To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and structures, such as anterior chamber depth, angle-to-angle width and sulcus-to-sulcus width. Measurement also may be made of pathologic structures such as solid masses or cysts and it is thus useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

Please do not write below this line—continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) ✓

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003890